REMARKS

Election/Restrictions:

Restriction to one of the following inventions has been required under 35 U.S.C. 121:

I. Claim 23 and 24, drawn to ONE anti-cancer antibody, classified in class 530, subclass 387.1.

(Upon election of Group I, applicant must further choose ONE anti-cancer antibody from claims 23 or 24, irrespective of the method of production of said antibodies, as each antibody represents an independent invention, not a species.)

II. Claims 1-22, drawn to a method for treating a patient suffering from a cancerous disease by administering ONE anti-cancer antibody, classified in class 424, subclass 130.1.

(Upon election of Group II, applicant must further choose ONE anti-cancer antibody from claims 1 or 12, irrespective of the method of production of said antibodies, as each antibody represents an independent invention, not a species.)

III. Claims 25-26, drawn to a method for the detection of cancerous cells in a tissue sample by contacting an isolated monoclonal antibody with said tissue sample, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

The restriction of the anti-cancer antibodies as independent inventions is alleged by the Examiner to be proper. In accordance with the decisions in In re Harnisch,.631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), the Examiner has indicated that restriction of a Markush group is proper where the compounds

within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, the Examiner points out that a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 USC 103.

Thus, the Examiner concludes that the inventions are unrelated because:

1) the biological process involved in antibody generation is variable and unpredictable in nature;

2) the structural differences generated by these processes allow the antibodies to recognize different epitopes;

3) it is unlikely that any two antibodies, even those directed to the same epitope, have the same structure.

Thus, the anti-cancer antibodies of Groups I and II are deemed by the Examiner to be independent inventions.

The Examiner further takes the position that the inventions of Group I and the methods of Groups. II and III are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see MPEP § 806.05(h)].

In the instant case the Examiner's position is that the antibody products as claimed can be used in a materially different process such as affinity chromatography or immunoblotting, and that searching all of the claims (i.e., both Groups) would invoke a burdensome search because the inventions have been classified separately. Thus, the Examiner concludes that each invention has attained recognition in the art as a separate subject for inventive effort, and also requires a separate field of search.

Further the Examiner posits that the inventions of Groups II and III are materially distinct methods, which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. The invention of Group III is directed to a method of treatment involving the steps of administering to cancer patients anti-cancer antibodies conjugated to cytotoxic agents. However, the Examiner points out that the invention of Group III involves the distinct and unrelated steps of contacting monoclonal antibodies with tissue samples to detect the presence of cancerous cells, and that these groups also have unrelated objectives and criteria for success. The objective of Group II being to treat cancer patients with anti-cancer antibodies with success being a positive response to this treatment. The objective of Group III being the detection of cancerous cells in a tissue sample with success being the ability to detect these cancerous cells.

Regarding claims 3 and 14, such claims are deemed generic to the following patentably distinct species of "antibody conjugates":

1) toxins;

2) enzymes;

3) radioactive compounds; and

4) hematogenous cells

The products of the above species represent separate and distinct molecules with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Applicant has been required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of

the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, it is Applicants' understanding that the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Furthermore it is understood that until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained, and that withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. Additionally, it is understood that in order to retain the right to rejoinder in accordance with the above policy, applicant must amend the process claims, during prosecution, to require the limitations of the product claims, and that failure to do so may result in a loss of the right to rejoinder.

Accordingly, Applicants elect the Group I invention, claims 23 and 24, albeit restricted to the H460-22-1 antibody, which is equivalent to the antibody produced by the hybridoma cell line deposited with the ATCC Accession Number PTA-4622.

The instant amendment cancels elected claims 23 and 24 in favor of newly submitted claims 27-34. Claims of this format have been preferred in applications desiring to protect

subject matter of similar scope, e.g. U.S. Patent 7,009,040, issued 3/7/06.

In the event that election is required for claim 34, Applicant elects the species "cytotoxic moiety" for prosecution on the merits, but requests rejoinder of the non-elected species upon allowance of a generic claim.

CONCLUSION

Upon entry of the instant Preliminary Amendment, Applicants respectfully request an examination on the merits in the above-referenced application.

Respectfully submitted,

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